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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,132	07/23/2001	Rainer Mueller	RDID0073US	2393

7590

09/10/2003

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

18

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,132

Applicant(s)

MUELLER ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-7 and 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This office action is in response to an amendment filed 6/24/03. Claims 1-5 and 8-15 have been cancelled. Claims 16-23 have been added. Claims 6-7 and 16-23 are pending in this application. There are new grounds of rejection herein and therefore, this action is Non-Final. An IDS filed 5/1/03, Paper No. 3 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7, 16-20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-7 are rejected for reciting the sequence "according to" SEQ ID NO: 5. It is unclear if the meaning of the term "according to" is open (i.e. comprising) or closed (i.e. consisting of). Use of the term "according to" is indefinite as it fails to establish the metes and bounds of the gene sequences encompassed by the claimed language. It is unclear if the meaning of the term "according to" is open (i.e. comprising) or closed (i.e. consisting of). **This is a new rejection.**

Claim 16 recites the limitation "the alkaline phosphatase gene" in claim 16. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by amendment.**

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Claims 17-18 is rejected for reciting that the gene sequence “corresponds to” SEQ ID NO: 1. It is unclear if the meaning of the term “corresponding to” is open (i.e. comprising) or closed (i.e. consisting of). Use of the term “corresponds to” is indefinite as it fails to establish the metes and bounds of the gene sequences encompassed by the claimed language. **This is a new rejection.**

Claims 16-23 is unclear for reciting that the medium contains selection marker as the specification and the prior art defines selection marker as a resistance or selection gene that encodes resistance to antibiotics or drugs added to the medium. **This is a new rejection.**

Claims 19-20 are vague in that applicants recite use of yeast cell but do not recite how these elements are to be used. For example, applicants recite, “methylophilic yeast cells are used” but do not definitively indicate how it is utilized. Applicants also recite, “transformants are used” ” and “a second vector is used” but do not indicate how they are used. **This is a new rejection necessitated by amendment.**

Claim 22 recites the limitation "the alkaline phosphatase gene" in claim 22. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by amendment.**

Claim 22 is unclear for reciting that the yeast cells are transformed “more than one time” with a vector. As recited, selection for transformants that have incorporated multiple copies is performed following the multiple transformation steps. It is unclear how transformants that have incorporated multiple copies are differentiated from those that have incorporated single copies. **This is a new rejection.**

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Applicant's claims read on a broad genus of eukaryotic alkaline phosphatase genes.

Applicant's claims read on a genus of eukaryotic alkaline phosphatase.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants claim a vector comprising an alkaline phosphatase gene. Applicants disclose that SEQ ID NO. 1 is the cDNA sequence for bovine alkaline phosphatase, bIAPII, coding sequence and SEQ ID NO. 5 is a codon-optimized version of bIAPII. However, the genomic version of any of the recited gene is not disclosed by the specification, nor does the prior art apparently disclose the entire gene. While the cDNA may be known, not the entire gene has been characterized. Because all of the components of the gene such as regulation sequences,

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introns, and exons must be determined empirically in order to generate the alkaline phosphatase gene, applicant claims the gene without any disclosure about its structure. The skilled artisan would not conclude that applicant was in possession of viral vector comprising the claimed genes.

In the instant case, applicants have only disclosed an alkaline phosphates encoded by the SEQ ID NO 1 and SEQ ID NO 5. In the specification, applicant teaches that alkaline phosphatase proteins are dimeric, zinc-containing non-specific phosphomonoesterases. Further, applicant teaches that the alkaline phosphatase to be expressed should be highly active with a specific activity of >3000 U/mg but only disclose that the bovine intestine alkaline phosphates that has such specific activity (page 2, line 22-25). There is no actual reduction to practice or clear depiction of what structures or properties correlate with alkaline phosphate with the claimed biochemical activity. Neither applicant nor the prior art provide a correlation between the structure of alkaline phosphatase and its function. Given the large size of a family of proteins derived from all eukaryotic organism and the diversity of proteins, variations, fragments and homologs that may be considered as alkaline phosphatase proteins, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

September 8, 2003


GERRY LEFFERS
PRIMARY EXAMINER